UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

VIROPHARMA INCORPORATED, 397 Eagleview Boulevard Exton, PA 19341 **Plaintiff,** **v.** **DEPARTMENT OF HEALTH AND HUMAN SERVICES, and FOOD AND DRUG ADMINISTRATION,** **Defendants.**	)	**Civil Action No. 08-_____ ( )**

COMPLAINT

1. This is an action under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, challenging the failure of the Food and Drug Administration ("FDA") and the Department of Health and Human Services ("HHS") (collectively, "FDA") to respond to Plaintiff ViroPharma Incorporated's two-and-a-half-year-old request for agency records. While FDA has acknowledged receipt of ViroPharma's FOIA request, it has never provided a substantive response, thereby constructively denying the request and improperly withholding the records.

2. ViroPharma's FOIA request sought records relating to FDA's decision to change its longstanding interpretation of its regulations that firms seeking to manufacture copies of ViroPharma's drug Vancocin® (vancomycin hydrochloride capsules) must show that a proposed generic copy is "bioequivalent" to Vancocin by testing it in humans (known as "*in vivo*" studies). Bioequivalence is required under both the Federal Food, Drug, and Cosmetic Act ("FFDCA"),

21 U.S.C. § 355(j)(2)(A)(iv), and FDA regulations, 21 C.F.R. § 320 (2008). ViroPharma submitted the FOIA request upon learning in March 2006 that FDA, without any notice or public process, had privately disclosed to certain third parties that henceforth *in vitro* laboratory testing alone (*i.e.*, not human testing) would be sufficient to show bioequivalence.

3. By changing its interpretation of the bioequivalence requirement without any notice or process, FDA violated the Administrative Procedure Act, 5 U.S.C. § 701 *et seq.* ("APA"), the FFDCA, and other federal statutes and regulations. Neither ViroPharma, the scientific community, nor the public at large had any prior notice of this significant change in bioequivalence methods and thus had no opportunity to review the basis for or comment on the scientific validity of FDA's new method. Consequently, pursuant to FDA regulations, ViroPharma submitted a petition to FDA to stay any approvals of drug products based upon the new method. ViroPharma also submitted the FOIA request that is the subject of this litigation to obtain the information necessary for ViroPharma, the scientific community, and the public to understand fully the basis for, and respond to, FDA's change in bioequivalence methods for Vancocin.

4. Without the requested records, to which ViroPharma has a statutory right, ViroPharma is significantly hampered in its ability to exercise its rights to review and comment on FDA's action, develop its petition to stay approvals of generic copies of Vancocin, and bring any other claims open to ViroPharma.

5. ViroPharma seeks declaratory and injunctive relief. ViroPharma seeks a declaration that FDA is in violation of the FOIA and an order directing FDA to produce the requested records in accordance with the FOIA.

JURISDICTION AND VENUE

6. This Court has subject matter and personal jurisdiction over FDA and HHS pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. §§ 1331, 1361, 1651.

7. Venue is proper in this district under 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391.

PARTIES

8. Plaintiff ViroPharma Incorporated is a small pharmaceutical company incorporated in Pennsylvania in 1994 and headquartered in Exton, Pennsylvania. ViroPharma develops and markets innovative medicines.

9. Defendant Department of Health and Human Services is an agency of the United States, and has responsibility under the FFDCA for regulating drugs marketed in the United States. 21 U.S.C. §§ 301 *et seq*. HHS is an agency for purposes of FOIA. *See* 5 U.S.C. § 551(1); 5 U.S.C. § 552(f)(1).

10. Defendant FDA is an agency of the Department of Health and Human Services, and is responsible for regulating drugs marketed in the United States. 21 U.S.C. § 393. FDA is an agency for purposes of FOIA. *See* 5 U.S.C. § 551(1); 5 U.S.C. § 552(f)(1).

11. FDA has possession and control over the records plaintiff seeks.

STATUTORY FRAMEWORK

12. The FOIA, 5 U.S.C. § 552, requires agencies of the federal government to release requested records to the public unless one or more statutory exemptions apply.

13. An agency must respond to a party making a FOIA request within 20 working days, notifying that party of at least the agency's determination whether or not to fulfill the request and of the requester's right to appeal the agency's determination to the agency head.

5 U.S.C. § 552(a)(6)(A)(i). Similarly, an agency must respond to appeals of the agency's response to a FOIA request within 20 days of receipt of the appeal. 5 U.S.C. § 552(a)(6)(A)(ii).

14. This Court has the power, upon receipt of a complaint, "to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant." 5 U.S.C. § 552(a)(4)(B).

15. A final order, opinion, statement of policy, interpretation, or staff manual or instruction that affects a member of the public may not be relied upon or used by an agency against a party unless it has been indexed and either made available or published, or the party has actual and timely notice of the terms thereof. 5 U.S.C. § 552(a)(2).

FACTS GIVING RISE TO PLAINTIFF'S CLAIMS FOR RELIEF

16. Since acquiring the product in 2004, ViroPharma has been the sole distributor of Vancocin in the United States.

17. Vancocin is one of only two drugs ViroPharma markets and is ViroPharma's primary source of revenue. Vancocin is used primarily to treat life-threatening gastrointestinal infections caused by *Clostridium difficile* ("*C. difficile*") bacteria. Vancocin is the only drug FDA has approved to treat *C. difficile* infections. Dramatic increases in both the occurrence and severity of *C. difficile* infections, including a new highly toxic and more lethal strain of the infection, have prompted federal officials to describe *C. difficile* as an epidemic.

18. Under the FFDCA, a party can seek FDA's approval to market a generic copy of an FDA-approved drug. Parties may seek such approval by filing an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. § 355(j). An ANDA applicant can rely on the findings of safety and efficacy for the innovator drug, provided the proposed generic drug is shown to be the *same* as the innovator drug.

19. To show sameness to the innovator drug, a generic applicant must establish that the proposed generic copy is "bioequivalent" to the innovator drug. Together with other requirements, a showing of bioequivalence enables a generic copy to be considered equally safe and effective as the innovator drug. *See* 21 U.S.C. § 355(j)(2)(A); 21 C.F.R. § 314.94; FDA, *Approved Drugs With Therapeutic Equivalence Evaluations* vi (28th ed. 2008).

20. Bioequivalence must be determined through *in vivo* studies, unless a waiver of such testing is issued pursuant to FDA's regulations. *See* 21 C.F.R. §§ 320.21, 320.22.

21. For ANDA applicants seeking to copy Vancocin, FDA's longstanding interpretation of its regulations was that *in vivo* studies were required to demonstrate bioequivalence. In early 2006, FDA reversed this authoritative, established interpretation, disclosing to select third parties that for ANDA copies of Vancocin, waivers of *in vivo* bioequivalence testing could be requested based solely on *in vitro* dissolution testing.

22. FDA disclosed its change in bioequivalence methods for Vancocin in letters to two stock analysts and a law firm and, on information and belief, to other parties, including potential ANDA applicants for generic copies of Vancocin. FDA's letters explained how to conduct the *in vitro* dissolution test. They did not offer any basis for FDA's change to *in vitro* testing, nor did they seek to demonstrate that the *in vitro* method was scientifically valid.

23. Because FDA did not conduct any public process as it changed its interpretation of its bioequivalence regulations to permit waiver of *in vivo* studies for ANDA applicants seeking to copy Vancocin, ViroPharma was unaware when FDA's change in interpretation occurred. ViroPharma and the public did not learn of the change until one of the parties who had received letters from FDA, a stock market analyst from Canada, disclosed the change publicly, causing ViroPharma's stock market valuation to fall precipitously. ViroPharma quickly made

informal requests to FDA seeking a copy of FDA's letter to the Canadian stock analyst, but FDA refused, claiming the letter was confidential, despite the fact that the analyst had published a report on its contents.

24. No notice was published in the Federal Register—or anywhere else—that FDA was considering a change in bioequivalence methods for Vancocin. FDA did not propose the change for public comment of any sort.

25. Based on published media reports, FDA has reviewed ANDAs for generic copies of Vancocin based upon FDA's new *in vitro* bioequivalence method.

26. FDA's failure of process impairs ViroPharma's ability to assert several of its other legal rights. ViroPharma is significantly hampered before this Court, and before FDA, in challenging the substance of FDA's changed interpretation of its bioequivalence regulations regarding Vancocin because FDA conducted no public process leading up to the change, and subsequently has refused to disclose the administrative record regarding the change. The absence of public process surrounding FDA's changed regulatory interpretation violated procedural requirements of the Administrative Procedure Act, the FFDCA, and other federal statutes and regulations which require notice of proposed changes, explanation from FDA of its basis for proposing changes, and an opportunity for public comment. FDA's failure to conduct public process when it chose to permit a waiver of *in vivo* bioequivalence studies for Vancocin was also flawed because it treated ViroPharma differently from other similarly situated manufacturers of drugs for which FDA did conduct public process when proposing to change bioequivalence methods.

27. ViroPharma submitted a Petition for Stay of Action and a FOIA request to FDA precisely because FDA broke with its longstanding interpretation by stating that a waiver of

in vivo studies could be requested based on *in vitro* dissolution data alone, but did not explain the basis for this change or follow the requirements of the APA and other laws and regulations.

28. On March 17, 2006, after learning of FDA's actions and after FDA's refusal to share a copy of the letter it had sent the Canadian stock analyst, ViroPharma filed a Petition for Stay of Action with FDA, pursuant to 21 C.F.R. § 10.35. ViroPharma's petition sought to stay approval of any ANDA under FDA's new bioequivalence testing method. ViroPharma has submitted extensive legal and scientific materials in support of its petition, and members of the public and the medical profession also have expressed concerns to FDA regarding the non-public nature of its change in the bioequivalence method and the validity of the method itself. While the FDA has acknowledged receipt of the Petition for Stay of Action, it has not acted on it.

29. On March 21, 2006, ViroPharma, acting through its agent, Kathy M. McGown of the law firm FoxKiser, submitted a FOIA request to the FDA's Division of Freedom of Information, a component of HHS. *See* Exhibit A. The request complied with FDA regulations pertaining to FOIA requests. ViroPharma's request provided a reasonable description of the records sought. Specifically, ViroPharma requested:

> A copy of the entire administrative record of the decision of the Office of Generic Drugs (OGD) (including, but not limited to, documents related to reference number: OGD #06-0200) that abbreviated new drug applications (ANDAs) or applications filed under 505(b)(2) for vancomycin hydrochloride capsules qualify for a waiver of *in vivo* bioequivalence and may demonstrate bioequivalence to the reference listed drug Vancocin® through *in vitro* dissolution testing.

30. By letter dated March 27, 2006, FDA acknowledged ViroPharma's FOIA request, assigned a reference number to the request, and instructed that any questions be directed to the FDA's Division of Freedom of Information, a component of HHS. *See* Exhibit B.

31. After waiting in vain for some 19 months for FDA to answer its FOIA request, on November 20, 2007, ViroPharma, acting through its counsel, the law firm of FoxKiser, filed with HHS an administrative appeal of FDA's constructive denial of its FOIA request. *See* Exhibit C. ViroPharma's administrative appeal explained that the individual who submitted the FOIA request did so with the authorization and at the request of ViroPharma. ViroPharma attached to its administrative appeal a letter stating that the FOIA requester was authorized to and requested to submit the request on ViroPharma's behalf. The same letter demonstrated that FoxKiser was authorized to and directed to act on behalf of ViroPharma regarding the FOIA request and administrative appeal. ViroPharma requested expedited processing of its appeal pursuant to 21 C.F.R. § 20.44.

32. Over a month later, on December 27, 2007, HHS responded by letter to ViroPharma's administrative appeal. *See* Exhibit D. The letter acknowledged receipt of ViroPharma's appeal, assigned it a case number, and instructed that any questions regarding the appeal should be directed to the HHS Public Health Service Freedom of Information Office. The letter did not contain any other substantive information about ViroPharma's FOIA request or appeal.

33. Counsel for ViroPharma contacted FDA on December 1, 2008 as a courtesy, prior to filing this Complaint, and advised FDA that the Complaint would soon be filed. In response, counsel for FDA stated to ViroPharma's counsel that FDA would soon be releasing information regarding Vancocin that could "vitiate the need" for filing this FOIA action. As a result, FDA's counsel suggested that ViroPharma delay filing this Complaint until it reviewed the information that FDA was about to release regarding Vancocin. On the basis of that representation from FDA, in good faith, ViroPharma did not file this Complaint. FDA yesterday released, and today

published, a "Draft Guidance for Industry on Bioequivalence Recommendation for Vancomycin HCl; Availability." *See* Exhibit E ("Draft Guidance"). The Draft Guidance does not include the administrative record for FDA's March 2006 decision to change bioequivalence methods for vancomycin, as sought in the FOIA request, or the data supporting that change. Thus, the Draft Guidance in no way vitiates the need for FDA to respond to ViroPharma's FOIA request. FDA's representation to ViroPharma's counsel that the information regarding Vancocin could be responsive to its FOIA request represents yet another example of FDA's almost three-year effort to frustrate ViroPharma's attempt to obtain the administrative record relating to Vancocin so as to permit it to assert its legal rights.

34. Indeed, the Draft Guidance—described as a clarification of FDA's 2006 decision on bioequivalence for Vancocin—confirms that FDA failed to engage in any public process before its 2006 decision and that FDA selectively disclosed the changed bioequivalence methods for Vancocin "to those parties that had requests pending with FDA for this information." Despite ViroPharma's requests, FDA did not provide that information to ViroPharma. Moreover, although FDA establishes a 60-day comment period for the Draft Guidance, by withholding the administrative record requested by ViroPharma, FDA hampers ViroPharma's ability to challenge the change in bioequivalence method.

35. FDA and HHS have not otherwise responded to ViroPharma's FOIA request or appeal and FDA has not disclosed any records to ViroPharma. FDA has not claimed that the records are exempt from disclosure.

36. ViroPharma has a statutory right to the records it seeks, and there is no legal basis for FDA's refusal to disclose them.

37. ViroPharma also has a statutory right that FDA not review ANDAs that seek to copy Vancocin based on FDA's changed interpretation of its bioequivalence regulations regarding Vancocin because FDA has not indexed, made available or published the terms of FDA's changed interpretation, and ViroPharma has not had actual or timely notice thereof.

38. ViroPharma has exhausted its administrative remedies.

39. Without the requested records, ViroPharma is significantly hampered in its ability to exercise its rights by developing its petition to stay approvals of generic copies of Vancocin, to comment on the Draft Guidance, and to bring any other claims open to ViroPharma.

VIROPHARMA'S CLAIMS FOR RELIEF

CLAIM ONE

(Unlawful Withholding of Agency Records Under FOIA)

40. Plaintiff realleges and incorporates by reference all preceding paragraphs.

41. FDA has wrongfully withheld agency records requested by Plaintiff by failing to comply with the statutory time limit for the processing of Plaintiff's FOIA request, resulting in constructive denial of that request, and by continuing to withhold responsive records.

42. Plaintiff has exhausted the applicable administrative remedies with respect to FDA's wrongful withholding of the requested records.

43. Plaintiff is entitled to injunctive relief with respect to the disclosure of the requested records.

PRAYER FOR RELIEF

Wherefore, Plaintiff respectfully requests that the Court:

(A) Declare that Defendant's withholding of the requested records is unlawful;

(B) Order Defendant to make the requested records available to Plaintiff;

(C) Award Plaintiff its costs and reasonable attorneys' fees pursuant to 5 U.S.C. § 552(a)(4)(E); and

(D) Grant all other appropriate relief.

Respectfully submitted,

Date: December 16, 2008

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